DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 1 3 2007

Re: Previcox
Docket No.: 2006E-0034

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,981,576, filed by Merck Frosst Canada & Company, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Previcox (firocoxib), the animal drug product claimed by the patent.

The total length of the regulatory review period for Previcox is 2,216 days. Of this time, 2,118 days occurred during the testing phase and 98 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 512(j) of the Federal Food, Drug, and Cosmetic Act involving this animal drug product became effective: June 29, 1998.

   FDA has verified the applicant's claim that the date the investigational new animal drug application (INAD) became effective was on June 29, 1998.

2. The date the application was initially submitted with respect to the animal drug product under subsection 512(b) of the Federal Food, Drug, and Cosmetic Act: April 15, 2004.

   FDA has verified the applicant's claim that the new animal drug Application (NADA) for Previcox (NADA 141-230) was initially submitted on April 15, 2004.

3. The date the application was approved: July 21, 2004.

   FDA has verified the applicant's claim that NADA 141-230 was approved on July 21, 2004.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Mitul I. Desai
Merck & Company
Patent Department
P.O. Box 2000
Rahway, NJ 07065-0907